K081054

Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

JAN 15 2009

1. **Company making the submission:**

	Company	or	Correspondent (contract):
Name:	Gish Biomedical, Inc.		Delphi Consulting Group
Address:	22942 Arroyo Vista Rancho Santa Margarita CA 92688-2600		11874 South Evelyn Circle Houston, TX 77071-3404
Telephone:	949-635-6240 voice 949-635-6294 fax		713-723-4080 voice 832-615-3550 fax
Contact:	Edward F. Waddell Director RA/QA edw@gishbiomedical.com		J. Harvey Knauss Consultant harvey@delphiconsulting.com

2. **Device:**

Proprietary Name:	Gish Arterial Filter with HA Coating
Common Name:	Arterial Filter
Classification Name:	Arterial Line Blood Filter, Cardiopulmonary Bypass

3. **Predicate Devices:**

Gish Arterial Filter, Gish Biomedical, Inc., K914791 and Gish Arterial Filter with GBS™ Coating, K023833. Both manufactured by Gish Biomedical, Inc.

4. **Classifications Names & Citations:**

21 CFR 870.4260, Arterial Line Blood Filter, Cardiopulmonary Bypass, Class II, DTM, Cardiovascular.

5. **Description:**

The Gish Arterial Filter with HA Coating is designed for use as the final filtration product in the arterial line of the extracorporeal bypass circuit. The top of the filter housing contains a vent port to assist in the priming and removal of air from the arterial filter.

The components of this system which have contact with the fluid path are sterile and nonpyogenic.

A filter bypass line may be used to enable blood to bypass the arterial filter should higher than normal pressures be observed on the inlet side of the arterial filter.

A four way stopcock is also provided for placement on the vent port of the arterial filter.

All materials of the arterial filter are biocompatible and coated with a proprietary coating.

The Gish Arterial Filter with HA Coating may be purchased separately or pre-connected with tubing and other components of an extracorporeal circuit.

6. **Indications for use:**

   The Arterial Filter with HA Coating is indicated for use for up to 6 hours in the extracorporeal bypass circuit for the removal of microemboli.

7. **Contraindications:**

   For HA coated arterial filters, no contra-indications have been noted.

8. **Comparison:**

   The Gish Arterial Filter with HA Coating has the same device characteristics as the predicate devices.

9. **Test Data:**

   The Gish Arterial Filter with HA Coating has been subjected to extensive safety, performance, and validations prior to release. Final testing for the systems includes various performance tests designed to ensure that the device meets all of its functional requirements and performance specifications. Safety tests have further been performed to ensure the device complies with applicable industry and safety standards.

10. **Literature Review:**

    A review of literature pertaining to the safety and effectiveness has been conducted. Appropriate safeguards have been incorporated in the design of Gish Arterial Filter with HA Coating.

11. **Conclusions:**

    The conclusion drawn from these tests is that Gish Arterial Filter with HA Coating is equivalent in safety and efficacy to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gish Biomedical, Inc.
c/o Ms. Janet Peets
Regulatory & Clinical Affairs Specialist
22942 Arroyo Vista Rancho
Santa Margarita, CA 92688-2600

JAN 15 2009

Re: K081054
Gish Arterial Filter with HA Coating
Regulation Number: 21 CFR 870.4260
Regulation Name: Arterial Line Blood Filter, Cardiopulmonary Bypass
Regulatory Class: Class II (two)
Product Code: DTM
Dated: January 8, 2009
Received: January 12, 2009

Dear Ms. Peets:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Inductions for Use Statement
(Per 21 CFR 801.109)

510(k) Number K 081054

Device Name: Arterial Filter with HA Coating

Indications for use:

The **Arterial Filter with HA Coating** is indicated for use for up to 6 hours in the extracorporeal bypass circuit for the removal of microemboli.

Prescription Device:

Federal Law (US) restricts this device to sale by or on the order of a physician.

Prescription Use YES OR Over-The-Counter Use NO

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081054